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8B.8

A biodegradable scaffold for the treatment of a diaphyseal bone defect of the tibia

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Purpose: The aim of our study was to evaluate bone formation and angiogenesis produced within a biodegradable poly-D,L-lactide-co-glycolide acid / calcium phosphate (PLGA/CaP) scaffold when used to treat a diaphyseal tibia defect.
Methods: Canine tibiae were reamed to 7.0 mm and fixed with a 6.5 mm statically locked intramedullary nail after creation of an 8.0 mm diaphyseal defect. Eighteen canines were allotted into 3 treatment groups: (1) empty ($N = 5$), (2) iliac crest autograft ($N = 6$), or (3) PLGA/CaP biodegradable scaffold (Tissue Regeneration Therapeutics Inc., ON, Canada) ($N = 7$).

Fluorescent labels were given at 6, 9, 11 and 14 weeks. Animals were sacrificed at 15 weeks and perfused with a barium compound. Samples were analyzed with radiography, Micro CT, and brightfield and fluorescent microscopy.
Results: Bone and vasculature volume within the tibial defect site were reported as a percentage of the total volume of the defect site. The percent bone volume within the defect site was not different between treatment groups ($p = 0.112$). There was greater percent vasculature volume in the scaffold group than the autograft group ($p < 0.001$).

Bone formation at the osteotomy sites was defined as the distance from the original osteotomy site to the tip of newly formed bone. Osteotomy bone formation was significantly greater in the scaffold group than the autograft group ($p = 0.015$). Osteotomy sites associated with greater angiogenesis displayed greater bone formation.

Bone formation rates were reported as the distance between the fluorescent bone labels. Autograft samples had the greatest bone formation rates within the periosteum. Autograft and scaffold samples had the greatest rate of bone formation within the cortex.
Conclusions: Our canine tibial defect model provides a satisfactory facsimile of the traumatic tibia fracture with associated bone loss. The PLGA/CaP biodegradable scaffold we have employed promotes angiogenesis within a defect and could be used with autografting.
Keywords: Bone defect; Scaffold for bone; Tibia fracture; Bone substitute

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8B.9

Results of use of bone morphogenic protein-2 (BMP-2) in the treatment of long bone fracture non-union—A series of 25 cases

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Introduction: Bone Morphogenic Protein 2 (BMP-2) has been used as a bone substitute in various orthopaedic procedures including spine surgery and acute high energy open tibial fractures with bone loss. There were no reported series in the literature in the use of BMP-2
Methods: We have treated 25 long bone fracture non-unions over a period of 2 years with BMP-2 during surgical fixation. We followed all the patients until union or failure requiring further surgery. Functional assessment was performed by short musculoskeletal functional assessment score (SMFA). 20 patients had BMP-2 only as the bone graft (group-1). 5 patients had iliac crest graft in addition to BMP-2 (group-2).
Results: There were 15 males and 10 females. Non-unions were spread across clavicle (4), humerus (3), ulna (2), femur (8), tibia (6) and lateral malleolus (2). 18 cases (90%) in group-1 and 5 cases (100%) in group-2 had clinical and radiological union. The mean time from original fracture to surgical intervention with BMP-2 was 15.21 months. Mean time from intervention with BMP-2 to further union was 7.43 months. There were no complications with use of BMP-2 either intra or postoperatively. The mean SMFA score has improved from 66.6 to 34.9.
Conclusion: BMP-2 may be an alternative to autologous bone grafting to avoid donor site morbidity in management of fracture non-union and can produce good results. Further studies with randomisation between autologous bone graft and BMP-2 will be required.
Keywords: Non-union; Fractures; BMP-2

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8B.10

BMPs and non-unions: A prospective randomised clinical study on 120 patients

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The purpose of this prospective randomised study, conducted between April 2005 and August 2007 at the Orthopaedic Institute G. Pini (University of Milan), was to compare the efficacy of recombinant bone morphogenetic protein 7 (rhBMP-7) and Platelet Rich Plasma (PRP) as bone-stimulating agents in the treatment of persistent fracture non-unions.

Long Bone NU is a very challenging condition that require adequate mechanical stabilization and often a concomitant biologic stimulation; to date, apart the use of Autologous Bone Graft (ABG) still considered the golden standard, Bone Growth Factors are available in clinical practice: recombinant human BMPs (rhBMP-7) or Autologous Growth Factors (AGFs) contained in Platelet Rich Plasma (PRP).

One hundred and twenty patients were randomised into two treatment groups (group rhBMP-7 vs group PRP). The number of males and females was 32 M–28 F for the rhBMP-7 group and 35 M–25 F for the PRP group. Sixty patients with sixty fracture non-unions were assigned to each group (median age: 46.4 ± 1.98 years for the rhBMP-7 group and 42.5 ± 1.76 years for the PRP group). Each patient underwent non-emergent operation for the treatment of their atrophic non-union, where adjuvant bone grafts were used according to the surgeon's preference. Revision of fixation method was implemented when deemed necessary.

In the rhBMP-7 group there were fifteen tibial non-unions, ten femoral, fifteen humeral, twelve ulnar, and eight radial non-unions. In the PRP group there were nineteen tibial non-unions, eight femoral, sixteen humeral, eight ulnar, and nine radial non-unions. The median number of operations performed prior to our intervention was 2.6 ± 0.62 and 2.7 ± 0.74 with autologous bone graft being used in twenty-three and twenty-one cases for the rhBMP-7 and PRP groups, respectively.